Exhibit 46

2016 WL 6652358
Only the Westlaw citation is currently available.
United States District Court, D. New Jersey,
Camden Vicinage.

IN RE: BENICAR (OLMESARTAN) PRODUCTS LIABILITY LITIGATION.

Master Docket No. 15-2606 (RBK/JS)
|
Signed 11/08/2016
|
Filed 11/09/2016

OPINION

KUGLER, United States District Judge

***1** Plaintiffs' submitted a request (Doc. No. 925) for leave to file a motion for partial summary judgement on the issue of general causation and accompanied it with fourteen (14) exhibits, either excerpts from defendants' depositions or documents produced by defendants. Plaintiffs assert the exhibits are defendants' admissions of general causation, which show that defendants' pharmaceuticals caused plaintiffs' complained of sprue-like enteropathy ["SLE"]. This opinion accompanies the order denying plaintiffs' request without prejudice (Doc. No. 938) and sets forth the reasons therefor.

I. Fact and Procedural Background

This Multidistrict Litigation ("MDL") involves approximately 1900 plaintiffs, who ingested defendants' olmesartan-containing prescription drugs[1] to alleviate hypertension. The named defendants are Daiichi Sankyo, Inc., Daiichi Sankyo Co., Ltd., Daiichi Sankyo U.S. Holdings, Inc., Forest Laboratories, LLC, Forest Laboratories, Inc., Forest Pharmaceuticals, Inc., and Forest Research Institute, Inc. The Daiichi defendants designed, manufactured and sold the drugs at issue.[2] For a time the Forest defendants marketed the drugs. Daiichi Sankyo, Inc. and Daiichi Sankyo U.S. Holdings, Inc. are U.S. companies. Daiichi Sankyo, Inc. is a wholly-owned subsidiary of Daiichi Sankyo U.S. Holdings, Inc. which operates as a holding company. Daiichi Sankyo Co., Ltd. is the parent company of Daiichi Sankyo U.S. Holdings, Inc. Daiichi Sankyo, Inc. operates as the commercial home office and U.S. corporate headquarters of Daiichi Sankyo Co., Ltd., which is a Japanese corporation with its principal place of business in Japan. *See generally* Master Answer of Daiichi Defendants ¶¶ 20, 23-27, 30-31 [Doc. No. 82].

In order to put the Plaintiffs' request in context, the court's management plan initially focuses only on general and specific causation issues, that is, whether defendants' drugs caused the complained of SLE symptoms, which include nausea, vomiting, diarrhea and weight loss.

To date, plaintiffs have taken at least twenty (20) depositions of present and former Daiichi U.S. employees and eighteen (18) depositions of present and former Daiichi Japan employees. The first phase of fact discovery regarding causation issues was all but completed by 30 September 2016;[3] the litigation has now entered the next phase with plaintiffs' causation expert reports due 30 November 2016, defendants' expert reports due 31 January 31, 2017, expert depositions to completed by 28 February 2017, and *Daubert* and summary judgment motions due by March 31, 2017. CMO No. 26. [Doc. No. 626]. The date for the *Daubert* hearing has not yet been set.[4]

***2** Turning to plaintiffs' request filed 13 October 2016 [Doc. 925], it comprises a summary of the 14 accompanying exhibits, which are excerpts of defendants' deposition testimony or defendant-produced documents, and characterizes them as admissions that defendants generally caused plaintiffs' injuries. Plaintiffs' request lacks not only an explanation as to how these summaries and excerpts constitute incontestable facts upon which to base a summary judgement motion but also any jurisprudential support that defendant alleged admissions during discovery in and of themselves properly substitute for expert testimony to demonstrate general causation.

Defendants argue that case law requires plaintiffs to offer admissible expert testimony on general causation because, in this case, linking the cause of each plaintiffs SLE injury to defendants' pharmaceuticals is beyond the ordinary understanding of a lay jury. Ds Response at 2. Defendants also argue that the excerpted testimony and documents are insufficient to unequivocally demonstrate that the pharmaceuticals caused the complained of injury in each of plaintiff's cases. *Id.* at 3.

The issue is whether the deposition excerpts and internal documents proffered by plaintiffs substitute as expert testimony reliable and fit under *Daubert v. Merrill Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993) to sufficiently inform a jury that defendants' pharmaceuticals caused plaintiffs' SLE in these cases.

II. Legal Standard

Courts generally recognize that plaintiffs in products liability cases must offer admissible expert testimony regarding both general causation and specific causation. *See, e.g.*, *In re Mirena IUD Products Liability Litigation*, ___ F. Supp.3d ____ (S.D.N.Y. 2016) 2016 WL 4059224 at *5, citing *Amorgianos v. Nat'l R.R. Passenger Corp.*, 303 F.3d 256, 268 (2d Cir. 2002; *see Rutigliano v. Valley Bus. Forms*, 929 F.Supp. 779, 783 (D.N.J. 1996), *aff'd sub nom. Valley Bus. Forms v. Graphic Fine Color, Inc.*, 119 F.3d 1577 (3d Cir. 1997) and further stating that "substantive law across all relevant jurisdictions holds (reference omitted) that 'where a causal link is beyond the knowledge or expertise of a lay jury, 'expert testimony is required to establish causation' (citations omitted)". *Id.*

Recently, the *Mirena* court found that, although there may be circumstances when defendants' admissions in a product liability case can substitute for expert testimony, those circumstances are "exceedingly rare". *In re Mirena* at *8. Expert testimony is generally required in product liability cases because it prevents the jury from engaging in speculation in determining the causal link between using or ingesting the product and the injuries complained of following that use. *Id.* at *5. Determining that causal link typically requires complex medical information beyond the knowledge, understanding, and experience of a lay juror. Expert testimony typically provides this link. *See generally* Christopher R.J. Pace, *Admitting and Excluding General Causation Expert Testimony: The Eleventh Circuit Construct*, 37 Am. J. Trial Advoc. 47, 51-60 (2013) (comparing the probative value of various general causation methodologies used by experts to support their testimony as *Daubert* reliable).

Purported admissions offered as substitutes for expert testimony must be "clear, unambiguous, and concrete" and suffice to prove general causation without speculation. *Id.* at *8. "They can substitute for expert testimony only when they serve the same purpose as expert testimony, that is, to provide the jury with a scientific, non-speculative basis to assess general causation." *Id.* at *12.

Also recently, a court in the Third Circuit analyzed an analogous issue—whether the plaintiffs were able to establish general causation with virtually no expert testimony, which had been excluded as inadmissible under *Daubert* and Federal Rule of Evidence (FRE) 702. *In re Zoloft Products Liability Litigation*, ___ F. Supp.3d ____ (E.D. Pa. 2016) 2016 WL 1320799. There, plaintiffs found themselves precluded from offering new expert testimony on the issue of general causation—whether Zoloft caused the complained of birth defects—and were left with arguing that other evidence established causation. Such other evidence included declarations by treating physicians of differential diagnoses, case reports by treating physicians of the occurrence of birth defects, defendants' internal documents including literature reviews and published studies relying on statistics about whether Zoloft was the cause of the complained of birth defects, foreign language documents that contained a warning against pregnant women's ingestion of Zoloft, and drafts of product documents. *Id.* at *9.

***3** The *Zoloft* court found that, taken together, plaintiffs' potentially admissible evidence supported only an association between the drug at issue and the complained of birth defect and therefore presented only a possibility of general causation. *Id.* at *10. The court found that "plaintiffs have not produced sufficient admissible evidence from which a reasonable factfinder could determine, by a preponderance of the evidence, that [the drug at issue] could have caused Plaintiff's injuries." *Id.*

Mirena and *Zoloft* resolve the issue raised by plaintiffs' request. Unless information characterized by plaintiffs as defendants' admissions provide to the jury evidence that is clear, unambiguous, and concrete and suffices to prove general causation without the jury's speculation as to complex medical issues, then such information does not substitute for *Daubert*-admissible expert testimony of general causation.

III. Discussion of Proffered Information by Plaintiffs

Each of the 14 exhibits will be reviewed for its sufficiency to substitute as expert testimony that demonstrates general causation without relying on a jury's speculation as to what the exhibit means.

Exhibit 1: 5 page excerpt (out of at least 461 pages) from the deposition of Crawford Parker, MD, defendants'

Senior Director of Clinical Safety and Pharmacovigilance ("CSPV") in the United States.

Plaintiffs' request provides no specific reason for including Dr. Parker's testimony, nor contextualizes this excerpt within the deposition as a whole. Dr. Parker's testimony relates to certain documents that Dr. Parker provided to Dr. Peter Green, apparently a medical consultant to defendants, in advance of an unidentified meeting at which SLE adverse events were to be discussed. These documents included: a January 2009 review by defendants of celiac disease AE reports; the defendants knowledge of the 2012 Mayo Clinic publication[5]; the FDA request to Defendants to review SLE adverse events; and a September 2012 review by defendants of SLE adverse events.

Despite plaintiffs' repeated attempts, the excerpt shows that Dr. Parker expressly declined to characterize the information in one of defendants' ROADMAP clinical study as "an analysis". Dr. Parker's testimony does not suffice to inform in a clear, unambiguous, and concrete way and without jury speculation as to the complex medical issues involved in determining the mechanism by which olmesartan may generally cause the complained of injuries. This exhibit does not substitute for *Daubert*-admissible expert testimony of general causation.

Exhibit 2. 1 page excerpt (out of at least 165 pages) from the deposition of defendants' employee in Japan, Akinori Nishiwaki.

Plaintiffs' request states no specific reason for including Nishiwaki san's testimony or contextualizes this excerpt within his deposition as a whole nor was Nishiwaki san's role for defendants identified.

Plaintiffs' attorney read the following sentence from an unidentified document: "Before identifying olmesartan as a cause of villous atrophy, we, too, had considered 30 percent of our seronegative patients to have unclassified sprue". Nishiwaki san was then asked to confirm the presence of the word "cause" in the sentence, which he did.

That this one sentence included the word "cause" and that the deponent affirmed the presence of that word is not a clear, unambiguous, concrete, or sufficient demonstration of general causation.

***4** *Exhibit 3. 5 page excerpt (out of at least 415 pages) from the deposition of Allen Feldman, MD, head of defendants' CSPV unit in the United States.*

Plaintiffs assert that Dr. Feldman "admitted that the only cause he could identify for the [symptoms] suffered by these patients was Olmesartan [emphasis added]." (Ps Letter Request at 4-5). When asked about the meaning of a statement in a Medwatch report[6] (specifically whether the most likely explanation for patients' symptoms was olmesartan given their history of ingestion and dechallenges and positive rechallenges of the drug), Dr. Feldman replied: "The only cause given here [in the Medwatch report] is olmesartan". Feldman Dep. 285:24.

Dr. Feldman was only asked to confirm what a certain Medwatch report states; he was not asked as a medical professional to admit that olmesartan caused plaintiffs' symptoms. Dr. Feldman's deposition testimony is not clear, unambiguous, concrete or sufficient as to demonstrate general causation.

Exhibit 4: Email of 2 pages dated 26 March 2015, sent jointly from Ford Parker, MD, the same employee as in Exhibit 1, Ulf Stellmacher, director of defendants' CSPV unit in Europe, and Hideki Tagawa, associate *manager of defendants' CSPV unit in Japan, to all employees in each of defendants' CSPV units (in the US, Japan and Europe).*

Having the subject of "Coding and Expectedness of Sprue-Like Enteropathy for Olmesartan and Olmesartan Combination Products", the email states that the code "Syndrome SLE" was added as an expected reaction to the US Product Insert ("USPI") on 3 July 2013 and to defendants' Company Core Data Sheets ("CCDSs") in September 2013. The email provides recommendations to defendants' CSPV on how to determine expectedness[7] because it is believed they may not understand SLE symptoms. To that end, the email identifies "Syndrome SLE" as including "nausea, vomiting and diarrhea, signs typical of olmesartan induced sprue-like enteropathy, such as weight loss." Exhibit 4, at ¶1. The apparent purpose here is to inform CSVP employees how Syndrome SLE will be reported (presumably by clinicians) and how to code that information in periodic safety reports to regulatory agencies.

***5** The email states: " 'Syndrome sprue-like' is currently the DSPD[8] (the "Daichii Sankyo Pharmaceutical Development" functional unit) recommended term in MedDRA Version

16.1"[9] and advises that a report coded as olmesartan-related intestinal villous atrophy should be handled as a sprue-like enteropathy report, in order to conform with the findings in the Mayo Clinic publication (Rubio-Tapio, *supra*) that first publicly reported that villous atrophy in olmesartan-takers was related to their SLE symptoms. Item 4 of the email recommends that, when a clear diagnosis of SLE is not reported (presumably by a clinician), symptoms of diarrhea, malabsorption, or weight loss should be coded not as SLE, but as separate reactions.

Although stating that there are signs typical of olmesartan induced sprue-like enteropathy, this exhibit expressly informs defendants' employees that these signs, when not accompanied by a clear diagnosis, cannot be reported as SLE. Since the exhibit on its face calls for a clinician's diagnosis before defendants will report olmesartan induced SLE, it cannot provide clear, unambiguous, and concrete proof of general causation. Without more, and in light of the entire email, the mere use by defendants of the term "olmesartan induced sprue-like enteropathy" does not suffice to inform a jury as to general causation.

Exhibit 5: Email from Dr. Ulf Stellmacher to Crawford Parker, MD, and Hideki Tagawa, dated to 16 Jan 2015, attaching a summary of the "3rd fatal SLE case we have just processed". The attachment is a Power Point of 3 slides apparently prepared by Dr. Stellmacher, director of defendant's CSPV unit in Europe.
Slide 2 states that villous atrophy was found in a 70 year-old man living in France who had been taking Olmetec® or Alteis®[10] for an unknown period and who had died. As defendant-manufactured equivalents to the pharmaceuticals issued here, the medications were for hypertension. The slide states that "Causality cannot be denied based on available information. Though diagnosis was not confirmed, this case represents SLE".

This exhibit does not detail the causal link between the injuries complained of and the drugs at issue and cannot demonstrate general causation.

Exhibit 6: 8 page excerpt (out of at least 84 pages) from the deposition of Hideki Tagawa, associate *manager of defendants' CSPV unit in Japan.*
Tagawa san is apparently being asked to comment on the Power Point in Exhibit 5 above. He confirms that it states the cause of the death of a 70 year-old man in France was an olmesartan drug. Tagawa Dep. 58: 9 to 60: 20.

He is then asked to comment on an unidentified Power Point and on other unidentified documents, which leaves this court no point of reference from which to review independently to what Tagawa san is attesting to. Tagawa san confirms that the unidentified Power Point states: (1) based on reports of SLE in the U.S., a causal relationship between olmesartan-containing drugs and severe diarrhea could not be denied; and (2) Japanese and U.S. package inserts were modified to add diarrhea as a serious side effect following the U.S. reports. *Id.* at 69-70. He also confirms that he wrote an email stating that U.S. and Japanese reports indicated that chronic diarrhea improves when olmesartan is stopped in most cases. He states that what he wrote in that email is based on what defendants' medical advisors had told him. *Id. at* 83-84.

***6** Although Tagawa san affirms that he wrote certain content relating to SLE and confirms the statements set forth in the documents before him, he clearly indicates he is not an expert able to independently attest to general causation. This exhibit cannot demonstrate general causation.

Exhibit 7: 3 page excerpt (out of at least 173 pages) from the deposition of Yasushi Hasebe, head of defendants' CSVP unit in Japan.
Plaintiffs' request does not contextualize this excerpt within the deposition as a whole.

Hasebe san was asked: "You're not denying that the olmesartan was one of the factors causing the severe diarrhea, dehydration and hospitalizations described in this adverse report. You're not denying that, right?" Hasebe Dep. 127: 14-19. He answers, "Correct, I think that's one of the factors". *Id.* at 127:21-22.

Inasmuch as Hasebe san's answer would lead to jury speculation as to what other factors caused the complained of injuries, the exhibit is not clear, unambiguous, specific or sufficient to demonstrate general causation.

Exhibit 8: 1 page excerpt (out of at least 152 pages) from the deposition of Mahmoud N. Ghazzi, M.D., Ph.D.
Plaintiffs' request states no specific reason for including Dr. Ghazzi's testimony or contextualizes this excerpt within the deposition as a whole nor was Dr. Ghazzi's role for defendants identified. Research from independent sources identifies Dr.

Ghazzi as defendants' Global Head of Drug Development, as well as Head of Daiichi Sankyo Pharmaceutical Department in the U.S.

In response to questions about Deposition Exhibit No. 3068, which was neither provided nor summarized, and which the court, therefore, could not review, Dr. Ghazzi confirmed that, in May 2014, defendants were starting to arrange a meeting with key European opinion leaders (presumably in the medical and scientific fields) to understand the mechanism of olmesartan and its effects on patients. Ghazzi Dep. 152: 11-16. The only rational inference to be drawn from this evidence is that defendants' employees do not fully understand the cause of SLE. This excerpt cannot substitute for *Daubert*-reliable testimony as to general causation.

Exhibit 9: 2 page excerpt (out of at least 290 pages) from the deposition of Oliseyenum MacDonald Nwose, M.D., defendants' head of medical affairs and "responsible for the Olmesartan drugs", according to plaintiffs' letter request.
Plaintiffs' request does not contextualize the excerpt within the deposition as a whole.

In response to the question whether it is more likely than not that olmesartan causes SLE and serious gastrointestinal problems in some patients, Dr. Nwose states there have been cases "where olmesartan has been associated with sprue-like enteropathy" (Nwose Dep. 289:8-14; 290:1-2) and adds that before forming a conclusion as to causation, he would have to "go back and review each of these cases individually". *Id.* at 290: 7-9.

Here, a possible medical expert eschews assigning the label of causation onto olmesartan for SLE symptoms until he has reviewed each case himself. On its face, Dr. Nwose's testimony is no substitute for expert witness testimony.

Exhibit 10. 1 page excerpt (out of at least 151 pages) from the deposition of Anthony Corrado, Defendants' Director of Commercial Regulatory Affairs from 2011 to 2015.
***7** Plaintiffs' request does not contextualize this excerpt within the deposition as a whole.

Mr. Corrado answers "there is a probability" to the question whether defendants agree that some patients do suffer severe gastrointestinal side effects from taking olmesartan-containing drugs. Corrado Dep. 151: 10-15. Mr. Corrado's answer does not resolve the issue of general causation because there is no elimination of other agents possibly causing SLE symptoms in olmesartan patients. This exhibit is not clear, unambiguous, concrete or sufficient to demonstrate general causation.

Exhibit 11: 4 page excerpt (out of at least 147 pages) from the deposition of Diane Benezra-Kurshan, M.D.
Plaintiffs' request does not contextualize this excerpt within the deposition as a whole and appears to identify Dr. Benezra-Kurshan as that member of defendants' Label Review Committee who drafted proposed warning language to physicians regarding olmesartan use. The date of the proposed warning language is unidentified but after the publication of the Rubio-Tapio article, *supra.*

Dr. Benezra-Kurshan is asked about the meaning of her proposed drug label and its message to physicians. She answers that the label would read to physicians that olmesartan is probably causing the SLE and advises physicians to stop drug ingestion and the SLE symptoms may go away. Benezra-Kurshan Dep. 133:1-8. She adds that the proposed label would also indicate to physicians that, when the drug is stopped, and patients don't improve, then causes other than olmesartan ingestion should be investigated. *Id.* at 147:9-14.

Although this excerpt speaks to defendants' knowledge and response, after the Rubio-Tapio article, *supra*, to the occurrence of SLE symptoms in relation to olmesartan ingestion, it does not suffice as clear, unambiguous, and concrete demonstration of general causation.

Exhibit 12: 12 page excerpt (out of at least 178 pages) from the deposition of Makoto Mizuno, defendants' employee in Japan, *who collaborated on the development of olmesartan.*
Mizuno san is asked: "Based on everything you've seen and the study that you were doing in your company with a team of people, you do agree that there is some number of people–we don't have to argue about how many—some people who do develop sprue-like enteropathy from taking olmesartan, correct?" Mizuno Dep. 177: 23 to 178: 5. He responds: "I think that some patients–among some patients who were taking olmesartan, there were some patients who developed sprue-like enteropathy". *Id.* at 178:8-12.

It is unclear why plaintiffs have proffered this exhibit as evidence of general causation since Mizuno san simply states there is a co-occurrence in some patients taking olmesartan

with their experience of SLE. The exhibit is not clear, unambiguous, and specific evidence sufficient to demonstrate general causation.

Exhibit 13: 27 page excerpt (out of at least 364 pages) from the deposition of Jeffrey Warmke, Ph.D., defendants' witness under Federal Rule of Civil Procedure 30(b)(6).

Dr. Warmke attests that defendants received reports of the occurrence of villous atrophy, and/or gastroenteritis, or collagenous colitis—symptoms complained of in this litigation—in three patients participating in their clinical ROADMAP studies.[11] Warmke Dep. 327:21 to 331:3; 340:18 to 345:18; 348:6 to 349:1. He also attests that defendants' analysts documented that two of these occurrences had a causal relationship to the olmesartan ingestion. *Id.* at 345:6 to 19; 349:13 to 350:10.

***8** Although this exhibit may support specific causation if the patients Dr. Warmke discussed are also plaintiffs in this matter, it does not resolve the issue of the general causation of injuries complained of by all plaintiffs here. *See generally* RESTATEMENT (THIRD) OF TORTS: LIAB. FOR PHYSICAL & EMOTIONAL HARM § 28 comment c (2010) ("The concepts of general causation and specific causation are widely accepted among courts confronting causation issues with toxic agents.").

Exhibit 14: 7 page excerpt (out of at least 137 pages) from the deposition of Dr. Katsuyoshi Chiba, defendants' employee in Japan.

Plaintiffs' request provides no specific reason for including Dr. Chiba's testimony or contextualizes this excerpt within the deposition as a whole nor identifies Dr. Chiba's role for defendants.

Particularly salient in Dr. Chiba's testimony in this exhibit are:

-"it is not possible to reproduce the results of the clinical studies by Mayo Clinic" (Dr. Chiba Deposition Transcript 59:7-8);

-"I think the best scenario would be that this will not be conducted by the non-clinical side" (referring to a non-clinical comparison test of olmesartan with other anti-hypertension drugs that also rely on the action of a TGF-β inhibitor, designed to determine whether all such hypertension drugs are linked to symptoms that plaintiffs complained of) (*Id.* at 64: 21-24);

-" it wasn't a matter of proving or not [the relationship between olmesartan and SLE] but rather it was not possible for us to carry out any kind of nonclinical studies with — with—in — in a reliable manner" (*Id.* at 65: 16-19).

This exhibit appears to relate to whether defendants' choice not to conduct non-clinical tests indicated a belief that such tests would show a causal connection between olmesartan ingestion and SLE symptoms. Dr. Chiba's testimony confirms that, since such a test was not conducted, there can be no information pointing to general causation and therefore cannot demonstrate it.

Conclusion

None of the exhibits proffered by plaintiffs either singly or in combination evidences in a clear, unambiguous, and concrete way the mechanism by which the olmesartan-containing drugs at issue may generally cause the complained of injuries. No exhibit or combination can resolve the inevitable jury speculation as to the complex biochemical, biological, and epidemiological information that underpins the general causation question here.

Consequently, this court declines to find or characterize whether any of the proffered exhibits is an admission by defendants under Federal Rule of Evidence 801(d) (2).

Accordingly, for all the reasons discussed above, plaintiff's Request to File Summary Judgement Motion on Submitted Exhibits has been DENIED in Doc. No. 938.

Dated: 11/8/2016.

All Citations

Not Reported in Fed. Supp., 2016 WL 6652358

Footnotes

1 These drugs are Benicar®, BenicarHCT®, Azor®, and Tribenzor®; they are collectively referred to herein as "olmesartan".

2 The Court will collectively refer to all the Daiichi party defendants as "Daiichi."

3 The Court granted plaintiffs leave to take some additional depositions after September 30, 2016, but cautioned this would not extend any other scheduling deadline. See September 1, 2016 Order at 3. [Doc. No. 874].

4 In addition to the cases in this MDL, approximately 73 related cases are consolidated in New Jersey State Court as Multicounty Litigation ("MCL"). Discovery in the federal MDL and state MCL has been coordinated. The Court anticipates a joint Daubert-type hearing will be held in the spring or summer of 2017. The state equivalent to Daubert is *Kemp ex rel. Wright v. State*, 174 N.J. 412 (2002).

5 A. Rubio-Tapio *et al.*, *Severe Spruelike Enteropathy Associated with Olmesartan*, Mayo Clin. Proc. 87(8), 732:738 (2012).

6 A MedWatch report is a voluntary report to the U.S. Federal Drug Administration (FDA) of an adverse event or undesirable effect associated with using a medical product, including pharmaceuticals and medical devices. The report can be prepared on a one-page FDA form or done via the telephone by health care professionals, patients, and consumers.

7 From a regulatory perspective and in relation to the periodic safety reports (titled in the U.S. as Development Safety Update Report ("DSURs")) provided to a national regulatory agency by the manufacturer of a drug either under development or that has been marketed and under further study, the term "expectedness" relates to whether a physiological reaction is a statistically expected side effect of the pharmaceutical. *Guidance for Industry. E2F Development Safety Report*, U.S. Department of Health and Human Services. Food and Drug Administration, prepared by International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), August 2011 (containing nonbinding recommendations), http://www.fda.gov/downloads/Drugs/.../Guidances/ucm073109.pdf.

When categorized as expected, a physiological reaction to drug ingestion must be clearly listed in the Reference Safety Information (RSI) of the DSUR provided by the drug manufacturer to the regulatory agency. *Id.* at 11, 14 and 23.

8 Defendants' unit that does pharmaceutical research, development, and marketing primarily in the U.S.

9 Developed by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), the Medical Dictionary for Regulatory Activities ("MedDRA") provides a globally standardized terminology to regulatory agencies (including the U.S. Food and Drug Administration, the European Medical Agency, and the Japanese Pharmaceutical and Medical Device Agency), pharmaceutical companies, clinicians, and translators, http://www.medra.org.

10 Olmetec® is a trademark registered in Japan to Daiichi Sankyo. Alteis™ is a brand name used by Daiichi Sankyo. These marks identify an olmesartan formulation equivalent to Benicar® and are used to market that in France. http://mpkb.org/home/mp/olmesartan/buying

11 Defendants conducted their own clinical studies of the olmesartan-containing drugs, which were designed to determine a reduction in the level of albumin in a patient's urine. Inasmuch as such albumin is a biochemical indicator of kidney disease due to hypertension, Defendants' ROADMAP tests were to some extent analyzing the statistical effectiveness of olmesartan ingestion on hypertension.

End of Document

Exhibit 47

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN PRODUCTS LIABILITY LITIGATION This Document Relates To: *All Actions*	Hon. Robert. B. Kugler Civ. No. 19-2875 (RBK/JS)

CONFIDENTIALITY AND PROTECTIVE ORDER

WHEREAS certain documents and information have been and will be requested, sought, produced, or exhibited by, between, and among the parties to the above- captioned action which involves the Valsartan products at issue and any future cases consolidated in this MDL (hereinafter "Action"), which relate to the parties' private proprietary information; trade secrets; proprietary scientific information; personal psychiatric, psychological, employment, and/ or medical information, and/ or other highly sensitive information, both business and personal; and,

WHEREAS, the Court finds that there is good cause for the entry of this Protective Order to protect "PROTECTED INFORMATION" from use in any manner inconsistent with this Protective Order;

IT IS ON THIS 26 day of JUNE, 2019 ORDERED THAT:

SCOPE OF PROTECTIVE ORDER

This Confidentiality and Protective Order ("Protective Order") applies to all hard copy and electronic materials and other products of discovery, all information contained therein and derived therefrom and including, but not limited to, all copies, excerpts, summaries or compilations thereof, obtained by the Plaintiffs or Defendants pursuant to the

requirements of any court order, any requirements of self-executing discovery, discovery requests under the Federal Rules of Civil Procedure; documents subpoenaed under the Federal Rules of Civil Procedure, affidavits, certifications, or otherwise, and transcripts of depositions and/or non-public or in camera hearings (hereinafter "Discovery Material"), produced by any party to this proceeding (the "Producing Party") to any other party (the "Receiving Party"), or disclosed by the Parties in discovery, and/or produced by non-parties and designated pursuant to paragraphs 14 and 15 below, and/or submitted to the Court in connection with a motion or hearing. Confidential Information shall be used and disclosed only for purposes of proceedings in the Litigation not for any other purpose or function, except as otherwise provided herein.

1. This Protective Order is binding upon the parties to the Action, including their respective corporate parents, subsidiaries and affiliates and their respective attorneys (including associates, assistants, paralegals and employees of counsel), agents, experts (whether testifying or consulting), consultants, representatives, officers, directors, joint venturers, and employees as set forth in this Order, or any party hereto or who shall become a party to this litigation, unless modified by the Court.

2. Third parties may avail themselves of, and agree to be bound by, the terms and conditions of this Protective Order and therefore become a Producing Party and/ or Receiving Party for purposes of this Protective Order.

3. Nothing herein shall be construed to affect or restrict in any manner the use or admissibility at trial or any other court proceeding of any document, testimony, or other evidence.

4. This Protective Order is not intended to address or govern claims of

privilege or work product that may otherwise be asserted by any of the parties, except to the extent provided in Paragraph 21 herein.

5. This Protective Order shall not be construed to protect from production or to permit the designation of any Discovery Material as "PROTECTED INFORMATION" that: the party (a) has failed to make reasonable efforts to keep confidential, (b) has lawfully obtained by or from another source, without breach of law, regulation, court order, or privilege, or (c) is at the time of production or disclosure, or subsequently becomes, through no wrongful act of the Receiving Party, readily accessible to others on a non-confidential basis. In the event the receiving party identifies any document it reasonably believes falls under this paragraph, it shall continue to treat the document as "PROTECTED INFORMATION" and follow the procedure set forth in Paragraph 20 of this Order.

6. Nothing in this Protective Order shall preclude any party or its representatives from inspecting, reviewing, using or disclosing its own "PROTECTED INFORMATION" in this litigation or in transactions or other matters unrelated to this case. To the extent the Designating Producing Party discloses any information previously designated as confidential, to another person or entity such that the information loses its confidential status, the Receiving Party is entitled to reasonably prompt notice that the information is no longer PROTECTED INFORMATION as defined in this Protective Order. No penalty shall accrue as a result of an inadvertent failure to do so.

7. Nothing shall prevent disclosure of "PROTECTED INFORMATION" beyond that required by this Protective Order if the Producing Party consents in writing to such disclosure.

8. This Protective Order does not relieve any party of its obligations to

respond to discovery in the Action and shall not restrict or limit the Defendants in any way from complying with regulatory obligations.

DEFINITIONS

9. The following definitions shall apply to this Protective Order:

A. "Authoring Party" shall mean any Party or its counsel who authored, drafted, or otherwise created the Document(s) at issue.

B. The term "CONFIDENTIAL INFORMATION" as used in this Protective Order means all information produced by any party in the course of discovery or other proceedings in this case (electronic or otherwise) which is proprietary, trade secret and/or highly sensitive commercial information, and which is believed in good faith by the Producing Party to have the potential, if disclosed, for causing competitive harm to it or giving a competitive advantage to others, and/or which is not publicly available and which a party believes in good faith to be subject to federal, state, or foreign data protection laws or other similar privacy obligations imposed by law. Examples of such data protection laws include, without limitation: India's Information Technology Act, 2000; India's Information Technology Rules 2011. Plaintiffs shall be permitted to designate materials that contain confidential personal information, confidential prescription drug benefit-related documents and/or records; beneficiary-related documents; drug utilization data; regulatory, and commercial information; trade secrets; correspondence with regulatory bodies; research, technical, commercial or financial information that has been maintained as confidential, information and documents required to be kept confidential by law or by agreement with a third party; and other non-public sensitive or proprietary information as "CONFIDENTIAL INFORMATION" pursuant to this Order. NOTE: It is anticipated that the volume of

documents to be exchanged by the parties during pre-trial discovery may be substantial. Accordingly, nothing herein shall be construed to prevent a Producing Party from designating documents as "CONFIDENTIAL INFORMATION" in order to expedite the flow of discovery and to facilitate discovery in these consolidated actions. The Court is confident that all parties and their counsel shall act in good faith at all times in making designations. Nonetheless, should it be demonstrated to the Court that a Producing Party has abused the discretion contemplated by the language of this paragraph and has unduly burdened their adversary, or that the party objecting to such designations has done so without a good faith basis for opposing the designations, an application for appropriate sanctions may be made.

C. "Copies" shall mean any photocopies, reproductions, duplicates, extracts, summaries, notes, or descriptions of Documents and/or PROTECTED INFORMATION.

D. "Designating Party" shall mean any Party or its counsel or any other person who has designated the Document(s) at issue as CONFIDENTIAL INFORMATION or RESTRICTED CONFIDENTIAL INFORMATION pursuant to paragraph 13, below.

E. "Document(s)" shall be defined as they are in Federal Rule of Civil Procedure 34, whether produced or created by a Party or another person, and whether produced pursuant to the Federal Rules of Civil Procedure, Local Rules, subpoena, by agreement, or otherwise. This shall include, but not be restricted to, all interrogatory answers, responses to requests for production or for admission, deposition testimony, deposition exhibits, hearing testimony, hearing exhibits, trial exhibits, and trial transcripts.

F. "Final Adjudication" shall mean the entry of a final, non-appealable order disposing of the Litigation or an individual action that is or will in the future become a part

thereof.

G. "Litigation" means the above-captioned litigation, including the Multi-District Litigation proceeding in the District of New Jersey, Case No. 1:19-md-02875, MDL No. 2875, and any individual cases direct filed in or transferred to the MDL.

H. "Party" shall mean a Party to this action, any employee of such Party, any counsel for such Party, and any paralegals or staff of counsel.

I. "Producing Party" shall mean any Party or its counsel or any other person who produced the Document(s) at issue.

J. "Product" means a Product at issue.

K. "PROTECTED INFORMATION" means Confidential Information and/or Restricted Confidential Information.

L. "Receiving Party" shall mean any Party or its counsel or any other person to whom PROTECTED INFORMATION is furnished.

M. "Restricted Confidential Information" means Documents that a Party has designated as "RESTRICTED CONFIDENTIAL" in accordance with this Protective Order and includes Documents a Party reasonably believes contain, describe, identify, or refer to highly confidential commercial, business, financial, or competitive information including proprietary manufacturing and production information (including formulation); business and prospective marketing plans; trade secrets; customer lists; pricing, market share, product cost and projected sales data; data relating to mergers and acquisitions; other information of a highly sensitive nature about the Party, which is not publicly available, the disclosure of which could cause the Producing Party competitive harm; and Protected Health Information ("PHI"), as that phrase is defined in the Health Insurance Portability

and Accessibility Act of 1996, Pub. L. 104-191 and the regulations promulgated thereunder. TPP Plaintiffs may further designate as "RESTRICTED CONFIDENTIAL" contracts (including drafts) between a TPP Plaintiff and third parties, including any Pharmacy Benefits Manager, any other document or communication that contains or recites the terms of such a confidential contract, and any documents which contain research and analysis that is known by a TPP Plaintiff to be proprietary to any Pharmacy Benefits Manager, and all documents reviewed by or created by any Pharmaceutical and Therapeutics Committee of any health plan or pharmacy benefit manager. Any Documents designated as RESTRICTED CONFIDENTIAL shall only be disclosed to the Party's outside counsel and shall not be disclosed to any Party, a Party's witnesses, or in house counsel unless either a) the designating party explicitly agrees to the disclosure in writing, or b) a successful challenge is made and disclosure is ordered by the Court pursuant to paragraph 20, below, except that the designating party may disclose their RESTRICTED CONFIDENTIAL documents in connection with the litigation or during deposition subject to the requirements of paragraph 29, below.

10. The following shall not be designated as "PROTECTED INFORMATION":

a. Documents of public record which are "readily accessible" as defined by Federal Law, or otherwise publicly available;

b. Documents filed as a public record with the clerk of any federal or state court, not including exhibits or depositions or discovery responses which, if filed, were to have been filed under seal and with clear marking on the envelopes in which they are enclosed that they are subject to this Protective Order or a Protective Order entered in

another case; [NOTE: Any exhibits, deposition transcripts or discovery responses filed "under seal" shall remain PROTECTED INFORMATION.]

c. Documents or articles published in trade magazines or other general circulation publications; or

d. Documents previously provided to any individual or entity on a non-confidential basis, or readily accessible to third-parties on a non-confidential basis.

11. No items or information, including but not limited to summaries of items or information designated as "PROTECTED INFORMATION" shall be produced or disseminated orally, or by any other means, except as permitted by this Protective Order.

12. Any designation of "PROTECTED INFORMATION" under this Protective Order shall not be construed as an admission or an agreement by any party:

a. That the designated disclosure constitutes or contains PROTECTED INFORMATION; or

b. That any document, material or information, or any portion thereof, constitutes competent, material, relevant, or admissible evidence in this case.

DESIGNATION OF "PROTECTED INFORMATION"

13. Subject to the admonition of the Court stated in Paragraph 9 hereinabove, the Producing Party shall designate PROTECTED INFORMATION by marking "CONFIDENTIAL INFORMATION" or "RESTRICTED CONFIDENTIAL INFORMATION" on the face of the document or material or, in the event

that PROTECTED INFORMATION is produced electronically or natively, on the disc or CD, on a placeholder document, and/or by such other means, including consistent with the ESI Protocol, so that the designation is communicated to the party receiving the document

14. **Notice of Designation of Non-Party Produced Documents**. Documents produced by a non-party must be treated by the receiving party as PROTECTED INFORMATION for a period of fourteen (14) days from receipt. In the event any non-party produces Documents or Information containing a Party's PROTECTED INFORMATION, that Party may designate such Documents or information, or portions thereof, as protected, pursuant to the provisions in paragraph 13 above, by providing notice of designation on all parties within fourteen (14) days of receipt.

If a Party otherwise receives Documents authored by a Party to the Litigation, from any source other than the Party who, upon reasonable and good faith inquiry, appears to have authored or created the Documents (i.e. the Authoring Party), the Receiving Party will notify the Authoring Party in writing within ten (10) days of receipt of the Documents. The notification shall include: (1) the bates numbers of the Documents received; (2) a brief description of the Documents; (3) the date received; and (4) the source of the Documents. Provided that such Documents are not publicly available, to the extent they contain PROTECTED INFORMATION but are not designated as such, the Authoring Party shall have the right to designate any such Document, or a portion thereof, as protected, pursuant to the provisions in paragraph 13 below.

This provision is not intended to abrogate a party's work product privilege, and a party may delay disclosure to an Authoring Party pursuant to this provision unless and until such documents are disclosed for use in the litigation, while treating the documents as PROTECTED INFORMATION during such period of non-disclosure.

15. **Non-Party Requests for PROTECTED INFORMATION**: Any Party to whom PROTECTED INFORMATION has been furnished who receives from any non-party (including natural persons, corporations, partnerships, firms, governmental agencies, departments or bodies, boards or associations) a subpoena or other process that seeks production or disclosure of such PROTECTED INFORMATION shall promptly, and in any case within three business days, give written notice by e-mail to counsel for the Designating Party so that the Designating Party may have adequate time before the Documents are to be produced to act pursuant to this Protective Order to guard against the disclosure of PROTECTED INFORMATION. The written email notice shall identify the Documents sought and the return date of the subpoena or other process, and the written notice shall also include a copy of the subpoena or other process. The Party receiving the subpoena shall also inform the person seeking the PROTECTED INFORMATION that such information is subject to this Protective Order. No production or other disclosure of such information pursuant to the subpoena or other process shall occur before the Designating Party approves the disclosure in writing or a Court order is issued on a timely filed motion to quash subpoena.

16. **Additional Parties**: If additional parties are added to this Litigation, then their or their counsel's ability to receive PROTECTED INFORMATION as set forth in this Protective Order will be subject to them or their counsel being bound by a written agreement or Court Order, to this Protective Order.

17. Subject to the admonition of the Court stated in Paragraph 9 hereinabove, all Documents and Copies produced or generated in this action pursuant to the discovery provisions of the Federal Rules of Civil Procedure, the Local Rules for the District of New Jersey, by order of this Court, or otherwise, and which contain, describe, identify or refer to PROTECTED INFORMATION shall be subject to the provisions of this Protective Order. Any Party shall have the right to designate, prior to production, any Documents or portion thereof, as CONFIDENTIAL INFORMATION or RESTRICTED CONFIDENTIAL INFORMATION pursuant to the following procedures:

A. Documents. For Documents in hardcopy form or in a modifiable electronic format: by affixing the following legend or stamp to each page of the Documents, or portion thereof, that is deemed "CONFIDENTIAL INFORMATION" or "RESTRICTED CONFIDENTIAL INFORMATION" in such a way so as not to obscure any part of the text or content, so that the designation is communicated to the party receiving the document. For electronically stored Documents (other than Documents in a modifiable electronic form): by affixing the following legend or stamp to the cover letter referring to such electronically stored Documents and, to the extent possible, to the media (i.e., disc, hard drive, etc.) on which the Documents are provided: "CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER" or "RESTRICTED CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER, " consistent with

the ESI Protocol, so that the designation is communicated to the party receiving the document.

Whenever any Party to whom electronically stored Documents designated as CONFIDENTIAL INFORMATION or RESTRICTED CONFIDENTIAL INFORMATION are produced reduces such Documents to hardcopy form, that Party shall designate the hardcopy Documents with the legend or stamp as provided below in paragraph 18.

B. Transcripts. All portions of any deposition or hearing transcript taken in the Litigation, wherein the Documents themselves, or the contents of the Documents, designated as PROTECTED INFORMATION are identified, discussed, or disclosed, shall also be designated as PROTECTED INFORMATION and shall be subject to the terms of this Protective Order. Within thirty (30) days after receiving a transcript, a Party may designate pages of the transcript and/or exhibits, or parts thereof to assure the minimum designations as reasonable, as PROTECTED INFORMATION by giving notice to all parties of same. PROTECTED INFORMATION within the transcript may be designated by indicating the portions of the pages that are confidential and marking such pages with the appropriate legend pursuant to the provisions above. Until expiration of the 30-day period, the entire transcript will be treated as RESTRICTED CONFIDENTIAL INFORMATION subject to protection against disclosure under this Protective Order.

An exhibit to a deposition shall be treated in accordance with any confidentiality designation or redaction previously given to it, and if not previously designated PROTECTED INFORMATION, then according to the designation later applied under this paragraph.

If no party or deponent timely designates PROTECTED INFORMATION in a transcript, none of the transcript will be treated as confidential. If a timely designation is made,

the portions and exhibits designated shall be filed only under provisional seal, separate from the portions and exhibits not so designated, and all Copies of the portions and exhibits so designated shall be treated as PROTECTED INFORMATION pursuant to the terms of this Protective Order. If any Party in good faith disagrees with a designation of any portion of a transcript or of any exhibit thereto as containing PROTECTED INFORMATION, the procedures regarding Challenges set forth in this Protective Order will govern.

18. **"CONFIDENTIAL INFORMATION/RESTRICTED CONFIDENTIAL INFORMATION - SUBJECT TO PROTECTIVE ORDER"**

Any Discovery Material for which it is impracticable or impossible to affix such a legend may be designated by written notice to that effect with a reasonable description of the material in question, and by designation on slip sheets where applicable. Such stamping or marking shall take place prior to, or contemporaneously with, the production by the Producing Party, or subsequent to the selection by the Receiving Party for copying but prior to the actual copying if done expeditiously. The stamp shall be affixed in such a manner as not to obliterate or obscure any written matter. The stamp need not be affixed to every page of a multi- page document.

Inadvertent production of any document or information without a designation of "CONFIDENTIAL INFORMATION" or "RESTRICTED CONFIDENTIAL INFORMATION" will not be deemed to waive a later claim to its protected nature or preclude a party from designating said document or information as "CONFIDENTIAL INFORMATION" or "RESTRICTED CONFIDENTIAL INFORMATION" pursuant to this Order at a later date, provided this is done within a reasonable time after production. Any party may designate as "CONFIDENTIAL INFORMATION" or "RESTRICTED

CONFIDENTIAL INFORMATION" or withdraw "CONFIDENTIAL INFORMATION" or "RESTRICTED CONFIDENTIAL INFORMATION" designation from any material that it has produced. A party must treat such documents and things with the noticed level of protection from the date such notice is received. A Party shall not be deemed to have waived any right to designate materials by allowing inspection of such materials prior to a designation. Such re-designation shall be accomplished by promptly notifying counsel for each party in writing of such re- designation. Upon production by the Designating Party of a set of the Documents containing PROTECTED INFORMATION marked CONFIDENTIAL INFORMATION or RESTRICTED CONFIDENTIAL INFORMATION, the Receiving Party shall reasonably promptly destroy the previously produced undesignated Documents or information. Upon receipt of any re-designation and replacement image that designates material as "CONFIDENTIAL INFORMATION – SUBJECT TO PROTECTIVE ORDER" or "RESTRICTED CONFIDENTIAL INFORMATION – SUBJECT TO PROTECTIVE ORDER," all Parties shall (1) treat such material in accordance with this Protective Order; (2) take reasonable steps to notify any persons known to have possession of any such material of such re-designation under this Protective Order; and (3) promptly endeavor to procure all copies of such material from any persons known to have possession of such material who are not entitled to receipt under this Protective Order, to the extent not already disseminated publicly.

19. Prior to producing documents that contain the names of patients other than Plaintiffs and/ or the physicians of such patients or consumers, the Producing Party may redact or delete the names, addresses, telephone numbers, social security numbers, and other information that would identify patients, research subjects and physicians or others constituting

voluntary reporters or any other person associated with an adverse event, and any other information required to be withheld from disclosure by 21 C.F.R. § 20.63, the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191 ("HIPAA") and related regulations, applicable federal and state privacy laws, and other applicable laws and regulations.

The Producing Party may redact information contained in adverse event reports, consumer complaints, clinical studies, and other similar Documents, including names and any information that would identify the person (other than a plaintiff or plaintiff's decedent) using the Product; names and any information that would identify any third party involved with the report, including, but not limited to, a physician or hospital or other institution; and personnel information that is not relevant to the issues in the litigation. If the Producing Party produces copies of documents containing the names or other personal information of patients other than Plaintiffs or their physicians that is protected from disclosure pursuant to 21 C.F.R § 20.63, HIPAA, or other governmental statute, rule or regulation, neither the Parties nor their counsel shall disclose the names or other personal information or contact any such patient or physician identified through the production of such documents. The prohibition does not apply, however, to information that was lawfully obtained through sources independent from the Producing Party's discovery productions. Nothing in this Section shall be construed to affect a Party's ability to redact irrelevant and/or non-responsive information from a Document, including information regarding other products or medications not at issue in this litigation.

20. A Party shall not be obligated to challenge the propriety of a "CONFIDENTIAL INFORMATION" or "RESTRICTED CONFIDENTIAL INFORMATION" designation at the time made, and failure to do so shall not preclude a subsequent challenge thereto. However, in the event a Receiving Party objects to such

designation of "CONFIDENTIAL INFORMATION" or "RESTRICTED CONFIDENTIAL INFORMATION," the following procedure shall apply:

(a) Counsel for the objecting party shall serve on the Producing Party or third party, and to Plaintiffs' and Defendants' Liaison Counsel, a written objection to such designation which shall describe with particularity the documents or information in question and shall state the grounds for objection. Counsel for the Producing Party or third party shall respond in writing to such objection within twenty-one (21) days of receiving the written objection, and shall state with particularity the grounds for asserting that the document or information is CONFIDENTIAL or ATTORNEYS' EYES ONLY. If no timely written response is made to the objection, the challenged designation will be deemed to be void. If the Producing Party or third party makes a timely response to such objection asserting the propriety of the designation, counsel shall then confer in good faith within fourteen (14) days of the date when the Producing Party's written response is dated in an effort to resolve the dispute.

(b) If a dispute as to a "CONFIDENTIAL INFORMATION" or "RESTRICTED CONFIDENTIAL INFORMATION" designation of a document or item of information cannot be resolved by agreement, the proponent of the designation being challenged shall present the dispute to the Court initially by telephone or letter, in accordance with Local Civil Rule 37.l (a)(l), within twenty-one (21) days of the date when the Producing Party's written response is dated) before filing a formal motion for an order

regarding the challenged designation. Failure to request said conference, or to file the motion shall operate as a waiver of the disputed designation. The document or information that is the subject of the filing shall be treated as originally designated pending resolution of the dispute. These time frames may be modified for good cause for specific challenges on informal application to the Court.

21. Inadvertent production of documents or information (hereinafter "Inadvertently Produced Documents") subject to the attorney-client privilege, the work-product privilege or other legal privilege or doctrine protecting information from discovery shall not constitute a waiver of the privilege or doctrine, provided that (1) the Producing Party shall notify the Receiving Party in writing of such inadvertent production within ten (10) business days after discovery of the inadvertent production, or (2) in the event the Receiving Party determines that such inadvertent production has occurred, the Receiving Party shall notify the Producing Party within ten (10) business of such discovery. In that event, such Inadvertently Produced Documents and all copies thereof shall be returned to the Producing Party or destroyed, upon request, and such returned or destroyed material shall be deleted from any litigation-support or other database, except as set forth below If, before being notified of the claim of privilege, a Receiving Party has already disclosed the Privileged Materials to others, the Receiving Party must take reasonable steps to attempt to retrieve the information or request that those to whom the information was disclosed, promptly destroy the Privileged Materials and any Copies. No use shall be made of such documents during depositions or at any hearing or trial, nor shall they

be disclosed to anyone who was not given access to them prior to the request to return or destroy them. If the party receiving the Inadvertently Produced Documents disputes the claim of privilege, work product, or other statutory or court-ordered protection, it shall within seven (7) days notify the Producing Party. In the event the parties are unable to resolve the dispute, either Party may contact the Court for the scheduling of a telephone conference call with counsel to review whether the designated Documents are rightfully subject to a lawfully recognized privilege. In the event the Court resolves the dispute, either Party may petition the Court via formal Notice of Motion within ten (10) days from the date of the conference call; otherwise the Court's resolution of the issue shall stand. In the event the Court does not resolve the issue, the Producing Party may petition the Court to maintain the asserted privilege or protection, within fourteen (14) days from the date of the conference call; otherwise the claim of privilege or protection shall be deemed withdrawn. Counsel for the Receiving Party may retain one copy of the inadvertently produced document(s) for purposes of opposing the motion and may submit the document for in camera review by the Court in connection with the motion. If the claimed privilege or protection is upheld or the challenge is waived, the document(s), along with any notes or other work product of the Receiving Party regarding the contents of such document(s), shall be destroyed or returned to the Producing Party. This Paragraph is intended to comply with Federal Rule of Evidence 502(d) and (e), and shall not limit the protections of attorney-client communications and work product provided by Federal Rule of Evidence 502.

LIMITATIONS ON DISCLOSURE OF "PROTECTED INFORMATION"

22. The parties agree that CONFIDENTIAL INFORMATION or RESTRICTED CONFIDENTIAL INFORMATION Documents and information shall not be used by any person receiving CONFIDENTIAL INFORMATION or RESTRICTED CONFIDENTIAL INFORMATION Documents and information for any business or competitive purpose and shall be used solely for purposes of this Litigation only and for no other action (litigation, arbitration, mediation, or other proceeding of any type) or purpose whatsoever (including, but not limited to, business, governmental, commercial, administrative, or judicial proceedings).. Except as allowed pursuant to paragraph 24 below, the Documents designated CONFIDENTIAL shall not, without leave of this Court, be disclosed to any person or entity other than this Court (under seal) and the Parties to this action and their counsel. The Documents designated RESTRICTED CONFIDENTIAL shall not, without leave of this Court, be disclosed to any person or entity other than this Court (filed under seal in accordance with Local Rule 5.3) and the Receiving Parties' external litigation counsel and the Disclosing Party and its counsel.

23. All persons receiving or given access to "PROTECTED INFORMATION" in accordance with the terms of this Protective Order consent to the continuing jurisdiction of this Court for the purposes of enforcing this Protective Order and determining a remedy for a breach of the Protective Order.

24. "CONFIDENTIAL INFORMATION" shall not be disclosed to anyone other than the following categories of persons:

a. The Court (and any appellate court), including court personnel and any court-appointed special master;

b. Mediators, secretaries, paraprofessional assistants, and other

employees of such mediators who are actively engaged in assisting the mediators in connection with this matter;

c. Employees of counsel for Plaintiffs or Defendants who have responsibility for assisting in the preparation and trial of this action or any appeal herein to the extent reasonably necessary to render professional services in this lawsuit.

d. Employees of outside copying, document imaging, litigation and trial support, and facsimile services to the extent reasonably necessary to render professional services in this lawsuit;

e. The persons who authored or contributed to the preparation of the "CONFIDENTIAL INFORMATION";

f. Disclosure may be made to consultants or experts (hereinafter, "consultants/experts") employed by Plaintiffs or Defendants, or their counsel, to assist in the preparation and trial of this litigation. However, prior to disclosure to any consultant/expert (including undisclosed consulting experts), the consultants/ experts must agree to be bound by the terms of this Protective Order by executing the acknowledgement annexed hereto as Exhibit "A". A copy of each executed acknowledgement shall be maintained for Plaintiffs' consultants// experts by Plaintiffs' Counsel, and for Defendants' consultants/ experts by Counsel for Defendants during the course of the litigation. At the conclusion of the litigation, counsel for Receiving Party shall confirm in writing with counsel

for Producing Party that it will seek to have any documents designated as "CONFIDENTIAL INFORMATION" that were provided to consultants/ experts returned to counsel for the Receiving Party.

g. In no event shall a Receiving Party make disclosure to litigation consultants/ experts who are serving or have served as non-litigation consultants, employees, officers, or directors of any competitors of Defendants, or anyone who at the time of disclosure is anticipated to become a non-litigation consultant, employee, officer, or director of any competitor of Defendants, except pursuant to the terms of this provision. In the event a Receiving Party wishes to make disclosure to any such litigation consultant/ expert, or to anyone who at the time of disclosure, is anticipated to become such litigation consultant/ expert, irrespective of whether they are retained as a consultant/ expert for Plaintiffs, the parties shall "meet and confer" to determine a method to address such proposed disclosure. If, after meeting and conferring, the Parties are unable to agree on a method to address such proposed disclosure, either Party may contact the Court for the scheduling of a telephone conference call for the Court to determine whether and under what circumstances such disclosure by the Receiving Party will be permitted. The Court may conduct an in camera review of the documents at issue, in its discretion. The Court's determination on these issues shall be binding on all Parties. Prior to a

determination by the Court on these issues, the Receiving Party may not disclose any CONFIDENTIAL INFORMATION to the proposed litigation consultant/ expert. A "competitor" shall be defined as an entity who is in the same business or commercial stream as the designating party, whether a pharmaceutical manufacturer or other company involved in the manufacturing, distribution, sale or marketing of Angiotensin Receptor Blockers or otherwise. Counsel for the Party who produced the subject CONFIDENTIAL INFORMATION shall be notified at least fourteen (14) days prior to disclosure to any person known to be an employee or agent of, non-litigation consultant to, any competitor of the Party whose designated documents are sought to be disclosed. Such notice shall provide a reasonable description of the person, and their affiliation with the competitor, to whom disclosure is to be made, sufficient to permit objections to be made. If a Party objects in writing to such disclosures within fourteen (14) days of receipt of notice, no disclosure shall be made until the Party seeking to make the disclosure obtains prior approval of the Court or the objecting Party.

h. The Parties to the extent required for assisting in the preparation and trial of each individual case or any appeal herein. To the extent such disclosure is made, such Party shall be advised of, shall become subject to, and shall agree in advance of disclosure to, the provisions of this Protective Order requiring that the material and

information be held as protected.

i. Deponents, Court reporters, videographers and their support personnel. Documents designated as "CONFIDENTIAL INFORMATION" may be shown to deponents during the deposition, but the deponent may not retain a copy of the document or have a copy of the transcript where the documents are discussed unless they have been informed of this Protective Order and has agreed in writing to be bound by it by executing Exhibit A to this Order.

25. All parties and their respective counsel, paralegals and employees and assistants of all counsel receiving Discovery Material, as well as any other individuals permitted to receive PROTECTED INFORMATION under any provision of this Protective Order, shall take all steps reasonably necessary to prevent disclosure of "PROTECTED INFORMATION" other than in accordance with the terms of this Protective Order.

26. Disclosure of "PROTECTED INFORMATION" other than in accordance with the terms of this Protective Order may subject the disclosing person to such sanctions and remedies as this Court may deem appropriate.

27. No "PROTECTED INFORMATION" shall be made or delivered to any person other than those categories of persons referred to in Paragraph 24 above.

28. "PROTECTED INFORMATION" may only be disclosed to persons who are not included in those categories referred to in Paragraph 24, above, upon prior written consent of the Producing Party's counsel. If the Producing Party's Counsel refuses to give consent, the "PROTECTED INFORMATION" shall not be disclosed. The party requesting disclosure may

apply to the Court via the procedure provided at Paragraph 20.

29. At the outset of the deposition of a non-party witness, the party proposing to disclose to the witness designated PROTECTED INFORMATION shall advise the witness and obtain his or her verbal confirmation or acknowledgment that the Court has Ordered that any disclosed PROTECTED INFORMATION may not be used for any business or competitive purpose and shall be used solely for purposes of this Litigation and for no other action or purpose. If after the deposition is taken the PROTECTED INFORMATION designation is stricken or removed, the defendants shall promptly notify the witness that this occurred. In the event that any question is asked at a deposition or non-public or in camera hearing, which a party asserts calls for "PROTECTED INFORMATION", or a document containing "PROTECTED INFORMATION" is identified as an exhibit in testimony given in this action, such question shall nevertheless be answered by the witness fully and completely to the extent required by law. While a witness is being examined about any PROTECTED INFORMATION, persons to whom disclosure is not authorized under this Protective Order may be excluded from being present by the Producing Party or its authorized designee, unless there is a legal basis to preclude exclusion. In the case of deposition or other non-public or in camera hearing testimony, or any exhibit thereto, the transcript, video or exhibit, or portions thereof, as applicable, may be designated as "PROTECTED INFORMATION" in accordance with this Protective Order by notifying the other party:

(1) on the record, at the time of the testimony; or

(2) in writing within twenty (20) days after the transcript has been received by counsel making the designation, specifying the testimony being designated protected by page and line number(s). Until the expiration of such 20-day period, the entire text of the

deposition transcript, including all testimony therein, shall be treated as RESTRICTED CONFIDENTIAL INFORMATION under this Protective Order.

The court reporter shall mark the face of the transcript with the label set forth in Paragraph 18 of this Order. Any court reporter or transcriber who reports or transcribes testimony in this case shall be informed before the beginning of the deposition or non-public or in camera hearing about this Protective Order and shall be asked to take reasonable and appropriate steps to preserve RESTRICTED CONFIDENTIAL INFORMATION. It is the obligation of the Producing Party to make any application to the Court with respect to the provisions of this paragraph. Should there develop any conflict between the timing provisions set forth in this Paragraph and the timing provisions regarding motion procedures set forth in Paragraph 31, below, Paragraph 31 shall prevail.

30. If a party receiving "PROTECTED INFORMATION" in accordance with the terms of this Protective Order is served with a subpoena or other process by any court, administrative or legislative body, or any other person or organization which calls for the production of any "PROTECTED INFORMATION" produced by another party, the party to whom the subpoena or other process is directed shall not, to the extent permitted by applicable law, provide or otherwise disclose such documents or information until ten (10) business days after notifying counsel for the Producing Party in writing of the following: (a) the information and documents that are sought by the subpoena; (b) the date on which compliance with the subpoena is requested; (c) the location at which compliance with the subpoena is requested; (d) the identity of the party serving the subpoena; (e) the case name, jurisdiction and index, docket, complaint, charge, civil action or other identification number or designation identifying the litigation, administrative proceeding or other

proceeding in which the subpoena or other process has been issued. The party receiving the subpoena or other process shall cooperate with the Producing Party in any proceeding relating thereto.

COURT SUBMISSIONS CONTAINING "PROTECTED INFORMATION"

31. Any documents that a Party wishes to file with the Court during this Action which have previously been designated as "PROTECTED INFORMATION" (or which contain CONFIDENTIAL INFORMATION or RESTRICTED CONFIDENTIAL INFORMATION), and all pleadings and memoranda purporting to reproduce or paraphrase such "PROTECTED INFORMATION," shall be filed in a manner that preserves the confidentiality of such information. To the extent possible, parties shall attempt to avoid the need to file materials under seal by working with the Producing Party to create non-confidential, redacted or excerpted pages of materials containing "PROTECTED INFORMATION" to attach to filings. Where the filing party has not had an opportunity to confer with the Producing Party, in advance of a filing, the filing party shall not attach materials containing "PROTECTED INFORMATION" to its filing but shall instead designate by Bates number the materials containing "PROTECTED INFORMATION" that would have been attached or completely redact all "PROTECTED INFORMATION" from such materials. No otherwise timely filing shall be considered late or incomplete if the filing attaches Bates numbers or redacted documents in place of materials containing "PROTECTED INFORMATION." Within ten (10) business days of the completion of briefing related to the filing, the filing party and Producing Party shall confer to determine whether they can agree upon non-confidential redacted or excerpted pages of materials containing "PROTECTED INFORMATION" to attach to the filing in place of the Bates

number designations or redacted materials. If the parties are unable to reach an agreement, then the designating party must file a motion to seal the materials containing "PROTECTED INFORMATION" pursuant to the requirements for doing so as set forth in Local Rule 5.3(c), and within thirty (30) days of the completion of briefing related to the original motion, or else waive confidentiality as to the materials containing "PROTECTED INFORMATION" at issue. If the Producing Party waives confidentiality as to the materials at issue, the filing party may replace the Bates number designations or redacted materials with the full text of the documents at issue.

32. If "PROTECTED INFORMATION" is filed under seal pursuant to the procedure established by Paragraph 31, and is ordered by the Court to be maintained under seal, the "PROTECTED INFORMATION" and/ or other papers shall be kept under seal until further order of the Court. However, said "PROTECTED INFORMATION" and other papers filed under seal shall only be available to the Court and counsel of record.

MISCELLANEOUS PROVISIONS

33. This Protective Order may be amended with leave of Court, or by the agreement of counsel for the parties in the form of a stipulation submitted to the Court for approval. If the parties cannot agree to an amendment, either Party may contact the Court for the scheduling of a telephone conference call with counsel to review whether the requested amendment is appropriate. In the event said conference call does not resolve the question to both sides' satisfaction, either may petition the Court via formal Notice of Motion. This Protective Order is intended to regulate the handling of "PROTECTED INFORMATION" during this litigation, but shall remain in full force and effect until modified, superseded or terminated on the record by agreement of the parties thereto or by

order of the Court.

34. Within thirty (30) days of the final termination of this case, whether by judgment, settlement or otherwise, (or such other time as the Producing Party may agree in writing), the parties shall return all "PROTECTED INFORMATION" to counsel for the Producing Party, and all copies thereof in his/her possession or subject to his/her control (including but not limited to materials furnished to consultants and/ or experts), or shall certify to counsel for the Producing Party that all such Discovery Material has been destroyed. Outside counsel shall not, however, be required to return or destroy any pleadings, pretrial or trial records as are regularly maintained by that counsel in the ordinary course of business, which records will continue to be maintained as "PROTECTED INFORMATION" in conformity with this Protective Order.

35. All rights available at law are reserved for any violation of this agreement.

36. **Applicability**

A. Generally. This Protective Order shall be binding throughout and after Final Adjudication of this action, including but not limited to, Final Adjudication of any appeals and petitions for extraordinary writs.

B. Waiver. Any Party may expressly waive in writing the applicability of any provision of this Protective Order to any Documents or portions thereof that the Party produces, or may effectuate a waiver pursuant to the terms of this Order. Such waiver shall apply only to the Documents or portions thereof to which the applicability of the specified provision of this Order is expressly waived.

D. Effective Date. This Protective Order shall become effective and binding upon each of the Parties and their undersigned counsel on the date the Court approves and enters this Protective Order.

If PROTECTED INFORMATION is disclosed in violation of this Protective Order, whether inadvertently or otherwise, the Party responsible for the disclosure shall use reasonable efforts to bind the recipient to the terms of this Protective Order, and shall (a) promptly inform the recipient of the terms of this Protective Order, (b) request the return of the PROTECTED INFORMATION and all Copies, and the destruction of work product and other materials reflecting the PROTECTED INFORMATION, and (c) request that the recipient sign a Declaration in the form of Exhibit A. If the recipient does not agree to sign a Declaration, the Party responsible for the disclosure shall identify the recipient immediately to the Party designating the PROTECTED INFORMATION.

G. Nothing in this Protective Order shall be construed to limit a Party's right to disclose to any person or use its own information or Documents including its own PROTECTED INFORMATION for any purpose.

H. Nothing is this Protective Order shall prevent a Party from using or disclosing information, including PROTECTED INFORMATION, obtained through discovery as necessary to meet reporting obligations to the F.D.A. or any governmental agency.

37. **Procedure Following Final Adjudication**

Within thirty (30) days after Final Adjudication of all cases within the Litigation:

1. The Clerk of Court shall maintain or dispose of all Documents filed under seal and designated as CONFIDENTIAL INFORMATION or RESTRICTED CONFIDENTIAL INFORMATION including, without

limitation, all transcripts or other things which were subject to the provisions of this Protective Order in accordance with the Federal Rules of Civil Procedure as well as the local rules of the District of New Jersey and any applicable orders regarding maintenance or disposal of sealed documents;

2. Parties and counsel having possession, custody or control of such Documents, transcripts, or other things designated CONFIDENTIAL INFORMATION or RESTRICTED CONFIDENTIAL INFORMATION shall completely destroy or return to counsel for the Producing Party, at the election of the Producing Party, the PROTECTED INFORMATION, except that Plaintiffs' counsel having multiple cases in the Litigation may fulfill these obligations after Final Adjudication of their last remaining case. This includes an obligation on the part of a Party to obtain and either return or destroy, at the election of the Producing Party, all such PROTECTED INFORMATION previously provided to outside experts and consultants and others who executed Exhibit A. Upon receipt of a written request for verification, counsel shall provide, within thirty days, a written verification of his or her destruction or return of the PROTECTED INFORMATION.

38. **Protective Order Not Admissible**

This Protective Order, including any discussion of the procedures and provisions herein, shall not be admissible in evidence. Counsel for a Party shall not, in the presence of the jury, comment on the Protective Order nor comment on the reasons or motivation for designating the

Documents as CONFIDENTIAL INFORMATION or RESTRICTED CONFIDENTIAL INFORMATION without first having obtained permission of the Court to do so.

39. **Amendment**

The parties reserve the right to move the court for an order to amend or to set aside this Protective Order, in whole or in part, upon good cause shown.

SO ORDERED, this 26th day of June, 2019

HON. ROBERT B. KUGLER

EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN PRODUCTS LIABILITY LITIGATION	Hon. Robert. B. Kugler
This Document Relates To: *All Actions*	Civ. No. 19-2875 (RBK/JS)

ACKNOWLEDGMENT AND AGREEMENT TO BE BOUND BY PROTECTIVE ORDER

The undersigned agrees:

I hereby attest to my understanding that the information or documents designated "PROTECTED INFORMATION" are provided to me subject to the Protective Order entered in In re Valsartan Products Liability Litigation, Docket No. 19-cv-2875, that I have been given a copy of and have read the Protective Order, and that I agree to be bound by its terms. I also understand that my execution of this Acknowledgment and Agreement to be Bound by Protective Order, indicating my agreement to be bound by the Protective Order, is a prerequisite to my review of any information or documents designated as protected pursuant to this Protective Order.

I further agree that I shall not disclose to others, except in accord with this Protective Order, any "PROTECTED INFORMATION", as defined therein, or any information contained in such "PROTECTED INFORMATION", in any form whatsoever, and that such "PROTECTED INFORMATION" and the information contained therein may be used only for the purposes authorized by this Protective Order.

I further agree and attest to my understanding that my obligation to honor the protected nature of such "PROTECTED INFORMATION" will continue even after this litigation concludes.

I further agree that if I fail to abide by the terms of this Protective Order, I will be subject to the jurisdiction of the United States District Court for the District of New Jersey for the purposes of any proceedings relating to enforcement of this Protective Order, and I specifically agree to subject myself to the jurisdiction of the United States District Court for the District of New Jersey for this purpose.

Date: _____ By: _____
(Signature)

_____
(Printed)

_____
(Street Address)

_____
(City, State and Zip Code)

_____
(Telephone)

Exhibit 48